DEC - 4 1996

16. **510(k) SUMMARY**

K964121

General Information

Date Prepared	September 26, 1996
Classification	Class III
Trade Name	WALLSTENT® Tracheobronchial Endoprosthesis
Common Name	Tracheal Endoprosthesis
Submitter	Schneider (USA) Inc 5905 Nathan Lane Minneapolis, MN 55442 (612) 550-5848
Contact	Cathy Yohnk Senior Regulatory Affairs Associate
Predicate Device	WALLSTENT® Tracheobronchial Prosthesis, K934116 WALLSTENT® Tracheobronchial Prosthesis, K945494 WALLSTENT® Tracheobronchial Prosthesis, K961296

Device Description

The WALLSTENT® Tracheobronchial Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. Smaller diameter models may utilize a radiopaque core. The prosthesis is a braided wire structure which may be covered with an elastomeric polymer in selected models. The outward radial force along with the ends of the device serve to stabilize the prosthesis after implanted. The prosthesis is offered in covered and uncovered version to allow physicians to select the most appropriate model based on their preference and individual patient

condition. The stent's purpose is to increase or maintain the inner lumenal diameter of the tracheobronchial passage.

The stent is placed by means of a delivery system. The delivery system is a coaxial tubing assembly which constrains the prosthesis until it is released in a controlled manner. The release of the stent is accomplished by retracting the outer sheath. The prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only.

Indication

The WALLSTENT® Tracheobronchial Endoprosthesis is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

The Schneider WALLSTENT® Tracheobronchial Endoprosthesis with Permalume® Covering is indicated for use in the treatment of tracheobronchial strictures or fistulas produced by malignant neoplasms, or in benign strictures or fistulas after all alternative therapies have been exhausted.

Technological Characteristics

The purpose of this 510(k) is to allow an alternate delivery system which allows the user to partially deploy and then reconstrain the stent to facilitate placement. This feature is presently available in the Esophageal delivery system (K940396). (The Classic™ delivery system which is used with covered stents is not a part of this submission.)

The alternate delivery system can be found substantially equivalent based on the results of *in vitro* and *in vivo* deployment testing which demonstrate that deployment forces and handling characteristics are comparable to the current delivery system.

Summary

In summary Schneider (USA) Inc believes the alternate delivery system is substantially equivalent based on design, test results, and indications for use.